(1)
Supreme Court, U.S.
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No. 02-

IN THE

Supreme Court of the United States

WILLIE C. NORMAN, individually,
and as representative of all persons at risk for lung cancer,

Petitioner,

v.

UNITED STATES PUBLIC HEALTH SERVICE; TOMMY G. THOMPSON, Secretary, DEPARTMENT OF HEALTH & HUMAN SERVICES; DAVID SATCHER, Assistant Secretary for Health and the Director of the Office of Public Health and Science; OFFICE OF PUBLIC HEALTH AND SCIENCE; ANDREW VON ESCHENBACH, Director of the National Cancer Institute; NATIONAL CANCER INSTITUTE; RANDOLPH F. WYKOFF, Director of the Office of Disease Prevention and Health Promotion; OFFICE OF PUBLIC HEALTH AND SCIENCE; ANDREW VON ESCHENBACH, Director of the Office of Disease Prevention and Health Promotion; OFFICE OF DISEASE PREVENTION AND HEALTH PROMOTION; UNITED STATES PREVENTIVE SERVICES TASK FORCE; JOHN M. EISENBERG, Director of the Agency for Healthcare Research and Quality; AGENCY FOR HEALTH CARE RESEARCH AND QUALITY,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

On Thursday, March 27, 2003, in the Orleans Parish Civil District Court, number 94-08546, New Orleans, Louisiana, a state court jury awarded JEAN VALETTE BERTHELOT, $636,506.00 as damages for the delay in the diagnosis of her breast cancer because her doctor failed to order a mammogram for her. The U.S. 5th Circuit called her case "frivolous" and this court denied her petition for certiorari on October 7, 2002, number 02-173.

The state court jury held that her doctor and her HMO failed to obey the State Law: La. R.S. 22:215.11 mandating HMOs to pay for mammograms starting at age 35. JEAN BERTHELOT proved that the National Cancer Institute ("NCI") has caused tens of thousands of American women, just like her, to lose their breasts and prematurely die, because her doctor and her HMO used the NCI's mammography guidelines as the standard of care for ordering mammograms starting at age 50.

Does WILLIE C. NORMAN have standing to challenge the NCI's decision to spend $200,000,000.00 DOLLARS, to conduct random clinical trials ("CLINICAL TRIALS") for the next 8 years to measure the mortality benefits from detecting lung cancer, instead of recommending Spiral CT screening for him and the other 91 million Americans who are at risk for lung cancer?

Is the NCI's refusal to follow the explicit order of the U.S. House of Representatives Committee on Government Operations not to rely solely on CLINICAL TRIALS to determine cancer screening guidelines — arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. 5 U.S.C. § 706(2). *See Sid Peterson.*[1]

1. *Sid Peterson Memorial Hosp. v. Thompson*, 274 F.3d 301, 308 (5th Cir. 2001).

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PETITIONER

WILLIE C. NORMAN, individually and as representative of all persons at risk for lung cancer similarly situated, respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Fifth Circuit in this case.

OPINIONS BELOW

The decision of the Court of Appeals dismissing WILLIE NORMAN's complaint is unreported. (per curiam, Jones, Stewart and Dennis, App. A). The District Court Opinion dismissing WILLIE NORMAN's complaint is reported, 2002 U.S. Dist. LEXIS 7391. (per Englehardt, D.J., App. B).

JURISDICTION

A. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

B. Court of Appeals jurisdiction is under 28 U.S.C. § 1291.

C. The district court's jurisdiction was under the Administrative Procedure Act (APA), which waives sovereign immunity for suits seeking relief other than money damages from federal agencies or officials. 5 U.S.C. § 702 *See Transohio.*[2] For claims under the APA federal jurisdiction may be proper under the federal question statute, 28 U.S.C. § 1331, the declaratory judgment statute, 28 U.S.C. §§ 2201-2202, or the mandamus statute, 28 U.S.C. § 1361.

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2. *Transohio Savs. Bank v. Director, Office of Thrift Supervision*, 967 F.2d 598, 607 (D.C. Cir. 1992).

REASONS FOR GRANTING THE WRIT

More than one million Americans will suffer serious pain and agony and will prematurely die due to the delay in the diagnosis of their lung cancer during the next 8 years the NCI will spend $200,000,000.00 DOLLARS conducting CLINICAL TRIALS to measure the mortality benefits from detecting lung cancer.

The dismissal of WILLIE NORMAN's APA case means that the NCI will not recommend Spiral CT screening to detect lung cancer.

The NCI in 2001, finally admitted there is a mortality benefit to detecting breast cancer early after denying there was a benefit for almost 10 years. The NCI has been and still is lying to the American public by publishing mammography guidelines contrary to the Federal Medicare law and the laws of more than 40 states since January 1, 1991, so insurance companies and HMOs can save money by paying for fewer mammograms than the Federal and State laws mandate.

The NCI is also lying about Spiral CT screening so insurance companies and HMOs can save money by not paying for Spiral CTs. It is less expensive for insurance companies and HMOs to let people die, rather than to pay for population screening to detect lung cancer early, when it can be treated.

NORMAN suggests that the U.S Fifth Circuit Court of Appeals has decided an important question of Federal law that has not been, but should be, settled by this Court.

STATEMENT OF THE CASE

This case arises from the failure of WILLIE NORMAN's doctors to order a Spiral CT scan for him to detect lung cancer. WILLIE NORMAN's doctors will not order a Spiral CT for him because the NCI does not recommend Spiral CT screening for people at risk for lung cancer.

WILLIE NORMAN filed a complaint against the NCI under the APA for injunctive relief. WILLIE NORMAN argues that the NCI's use of CLINICAL TRIALS to measure mortality benefits rather than recommending Spiral CT screening for people at risk for lung cancer, is arbitrary, capricious, an abuse of discretion, and not in accordance with the law. *See Sid Peterson.*[3] The district court found that WILLIE NORMAN had not been injured, did not have Article III standing, and dismissed his complaint on April 17, 2002. The Fifth Circuit affirmed the district court's dismissal without an opinion on January 17, 2003.

The NCI acknowledges that Spiral CT screening can detect lung cancer at a very early stage before it has a chance to spread.

On April 29, 1999 and again on September 23, 1999 the NCI made the decision not to recommend Spiral CT screening to detect lung cancer for persons at risk for lung cancer. The NCI decided to use CLINICAL TRIALS to measure mortality benefits not to recommend Spiral CTs, just like it decided to use CINICAL TRIALS to measure mortality benefits not to recommend mammograms to women under 50 years of age.

Why is lung cancer just like breast cancer? Why are Spiral CT scans to detect lung cancer just like mammograms

3. *Sid Peterson Memorial Hosp. v. Thompson*, 274 F.3d 301, 308 (5th Cir. 2001).

to detect breast cancer? Answer: because the NCI used the excuse of conducting CLINICAL TRIALS to measure mortality benefits — not to recommend them, so insurance companies and HMOs can save money by paying for fewer mammograms and Spiral CTs.

In December 1993, the NCI created the "mammogram fraud," when it published mammography guidelines contrary to the Federal Medicare law and the laws of more than 40 states, by refusing to recommend mammograms for women under 50 years of age. The NCI said CLINICAL TRIALS had not yet proven that women under 50 years of age live longer if their cancers are detected early.

The United States House of Representatives Committee on Government Operations (U.S. HOUSE COMMITTEE) conducted an investigation of the NCI's mammography guidelines and issued a report in October 1994, entitled: "Misused Science — The National Cancer Institute's Elimination of Mammography Guidelines for Women in Their Forties." The U.S. HOUSE COMMITTEE told the NCI it was wrong and that it "should change its policy of relying solely on CLINICAL TRIALS to determine cancer screening guidelines."

After the U.S. HOUSE COMMITTEE published "MISUSED SCIENCE," the NCI continued to target African American women with mammography guidelines starting at age 50, when the Federal and State laws start at age 35, even though the NCI knew African American women have a higher mortality rate due to breast cancer than white women do, because of their lack of access to mammography screening.

In February 1997, the NCI ignored the 1994 U.S. HOUSE COMMITTEE's report: "MISUSED SCIENCE," and recreated the "mammogram fraud" and again distorted the

entire body of public knowledge regarding mammograms by refusing to recommend mammograms to women under 50 years of age based upon CLINICAL TRIALS measuring mortality benefits.

In March 1997, the U.S. Senate voted 98-0 for the NCI "to reinstate the pre-1993 mammography screening guidelines." U.S. Senator Arlen Spector chaired a Senate Subcommittee that investigated the NCI's mammography guidelines. U.S. Senator Arlen Specter, quoted Dr. Daniel Kopans of Harvard Medical School, who called the NCI's guidelines: "Fraudulent."

After years of confusion about mammogram screening guidelines and the efficacy of mammograms caused by the NCI's lies, the U.S. Senate held two more hearings regarding the NCI's mammography guidelines, one in 2001, and one in 2002. In both hearings the NCI reversed itself and admitted CLINICAL TRAILS did show a mortality benefit when breast cancer is detected early.

The NCI's mammography and Spiral CT guidelines are based on CLINICAL TRIALS to measure mortality benefits. The NCI has been explicitly told by U.S. HOUSE COMMITTEE not to rely on CLINICAL TRIALS to determine cancer screening guidelines.

Mortality benefits are just one of the benefits from detecting cancer early. Cancer is much easier to kill when it is small and before it has metastasized. Detecting cancer early saves money, and reduces suffering to the patient. Detecting cancer early allows patients more treatment options. Detecting cancer early gives patients the opportunity to have a lumpectomy, rather than having their breasts, lungs or lymph nodes removed. Axillary dissection and chemotherapy may be reduced when cancer is detected early. Lung cancer

is potentially more curable when detected early. As cancer grows larger a person's long term survival rate decreases. Detecting cancer early gives patients greater control over what happens to their own bodies. "Detecting cancer early leads to a greater quality of life." — U.S. Senator Tom Harken.

The NCI's recommendation on population screening for the detection of cancer is the national standard of care in the absence of a federal or state mandated benefit law, like the Medicare law and the more than 40 state laws that mandate Medicaid, insurance companies and HMOs to pay for mammograms. Thus the NCI's recommendation for lung cancer screening is the national and local standard of care. Doctors must order the standard of care and Medicare, Medicaid, insurance companies and HMOs must pay for the standard of care.

The only way a patient can get a mammogram, or Spiral CT and have Medicare, Medicaid, an insurance company, or HMO pay for it, is if the patient's doctor orders it. The doctor will not order it, because the NCI does not recommend it. When the NCI recommends Spiral CTs to detect lung cancer, doctors will immediately have a duty to order them and Medicare, Medicaid, insurance companies and HMOs have the duty to pay for them. The failure of a doctor to order a Spiral CT for a person who is at risk for lung cancer will be a breach of duty, just like it was a breach of duty for JEAN BERTHELOT's doctor not to order a mammogram for her. A breach of duty is an unintentional tort. An unintentional tort is medical malpractice.

ARGUMENT

STANDARD OF REVIEW

The NCI's action not to recommend Spiral CT screening for people at risk for lung cancer should be held unlawful and set aside for the reasons set forth in 5 U.S.C. § 706(2).

ARTICLE III. STANDING

Recently the United States Supreme Court in *Laidlaw*[4] held that to satisfy Article III's standing requirements a plaintiff must show "injury in fact," causation, and redressability.

DOCTORS' DUTY TO ORDER THE STANDARD OF CARE

To understand WILLIE NORMAN'S case it is important to review some basic and general medical principles applicable to the practice of medicine. These principles were testified to by the expert witnesses in the *Corley*[5] case. These principles relate to the **duty** of a physician to formulate and revise a differential diagnosis.

Doctors are required to take a thorough history and perform a physical examination based upon the patient's signs and symptoms. Should the conclusions made from the medical history and physical examination support a diagnosis, the diagnosis should be made and the treatment instituted.

When a diagnosis can not be made, then a differential diagnosis should be made, which includes all reasonable, plausible, and foreseeable causes for the signs and symptoms

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4. *Friends of the Earth v. Laidlaw*, 528 U.S. 167, 1290 S. Ct. 693, 145 L. Ed. 2d 610 (2000).

5. *Corley v. State of Louisiana Department of Health & Hospitals, et al.*, 749 So. 2d 926, 932 (La. App. 2 Cir. 1999).

noted in the patient. Upon making a differential diagnosis, doctors have the *duty* to rule out all imminent, serious and life-threatening causes for the signs and symptoms. This includes preforming or *ordering diagnostic tests or studies*, which will assist in ruling in or out imminent, serious, and life-threatening causes.

Doctors are obliged to rule out these imminent, serious and life-threatening causes first. Failure to eliminate these causes can subject a patient to a foreseeable risk of harm and would further constitute a breach of the applicable standard(s) of care. *See Corley.*[6]

The NCI argues that WILLIE NORMAN had the duty to ask his doctors for the Spiral CT, which is the standard of care, and because WILLIE NORMAN did not ask for the Spiral CT, it is WILLIE NORMAN's fault the doctor did not order it.

However, patients do not have the duty to ask their doctors to order the diagnostic tests, which are the standard of care, for them. The foregoing basic medical principles show that it is the doctors' duty to order the diagnostic tests, which are the standard of care, for their patients and not the other way around, like the NCI wants this Court to believe.

INJURY IN FACT

The Supreme Court in *Laidlaw*[7] held that the relevant showing for the purposes of Article III standing is injury to the plaintiff — not injury to the environment. To require injury to the environment is to raise the standing hurdle higher than the necessary showing for success on the merits.

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6. *Corley v. State of Louisiana Department of Health & Hospitals, et al.*, 749 So. 2d 926, 932 (La. App. 2 Cir. 1999).

7. *Laidlaw* at 538 U.S. 181, (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61, 119 L. Ed. 2d 351, 112 S. Ct. 2130 (1992)).

In *Laidlaw*, the Supreme Court held that the plaintiffs did have standing because they alleged that one of them occasionally drove over the North Tyber River and that it looked and smelled polluted. The plaintiff testified that he wanted to fish, camp, swim and picnic in and near the river, but would not do so because he was concerned that the water was polluted by Laidlaw's discharges. Other members of plaintiffs' organization alleged that they no longer picnicked, camped, walked, birdwatched, hiked, swam, boated, or waded in the river, because they were worried about pollution.

The Supreme Court held that the plaintiffs had adequately alleged injury in fact because they use the affected area and are persons "for whom the aesthetic and recreational values of the area will be lessened" by the challenged activity. *See Laidlaw.*[8] "Of course, the desire to use or observe an animal species, even for purely esthetic purposes, is undeniably a cognizable interest for purposes of standing." *See Lujan.*[9]

In WILLIE NORMAN's case, his injury is the failure of his doctors to order a Spiral CT for him. WILLIE NORMAN has lost the right to determine what shall be done to his body. The right to determine what is done to one's own body is just as important as the right to observe an animal species, or to enjoy an unpolluted river.

The U.S. Supreme Court in *Cruzan*[10] held that "no right is held more sacred, or is more carefully guarded, by the common

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8. *Laidlaw* at 528 U.S. at 183, (citing *Sierra Club v. Morton*, 405 U.S. 727, 735, 31 L. Ed. 2d 636, 92 S. Ct. 1361 (1972)).

9. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 562-63, 119 L. Ed. 351, 112 S. Ct. 2130 (1992).

10. *Cruzan v. Director, Missouri Dep't of Health*, 497 U.S. 261, 269, 110 S. Ct. 2841, 2846, 111 L. Ed. 2d 224, 236 (1990) (citing *Union Pacific R. Co. v. Botsford*, 141 U.S. 250, 251, 35 L. Ed. 734, 111 S. Ct. 1000 (1891)).

law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law."

This notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment. Justice Cardozo, articulated this doctrine as: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who preforms an operation without his patient's consent commits an assault, for which he is liable in damages. *See Schloendorff.*[11] The informed consent law has become firmly entrenched in American tort law. *See* Keeton Dobbs, et al.[12]

In *Cruzan*,[13] the Supreme Court stated: "On balance, the right to self-determination ordinarily outweighs any countervailing state interests, and competent persons generally are permitted to refuse medical treatment, even at the risk of death. Most of the cases that have held otherwise, unless they involved the interest in protecting innocent third parties, have concerned the patient's competency to make a rational and considered choice."

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11. *Schloendorff v. Society of New York Hospital*, 211 N.Y. 125, 129-30, 105 N.E. 92, 93 (1914).

12. *See* Keeton Dobbs, Keeton & Owen, Prosser and Keeton on Law of Torts § 32 pp. 189-92; F. Rozovsky, Consent to Treatment, A practical Guide 1-98 (2d ed. 1990).

13. *Cruzan*, 497 U.S. at 273 (citing *In re Conroy*, 98 N.J. 321, 353-54, 486 A.2d 1209, 1225 (N.J. 1985)).

True consent to what happens to one's self is the informed exercise of a choice, and that entails the opportunity to evaluate knowledgeably the options and the risks. From these general principles, however, the focus in each individual case must necessarily relate back to what the physician said or failed to say and what the law requires him to say. *See Karp.*[14]

The loss of the right to determine what happens to one's own body, the loss of a chance of survival, the loss of part of a patient's medical history, the reduction in a patient's quality of life, and the delay in the diagnosis of cancer, have all been recognized as injuries and all result from a doctor's failure to order the standard of care, a diagnostic test, such as a Spiral CT scan, for a person who is at risk for lung cancer.

The NCI made the decision not to recommend JEAN BERTHELOT's mammogram, and WILLIE NORMAN's Spiral CT. The NCI took from them the right to be screened for breast and lung cancer. This is a concrete identifiable injury to them. The Louisiana Supreme Court in *Lugenbuhl*[15], cited Justice Cardozo and awarded $5,000.00 to the plaintiff for the loss of the right to determine what shall happen to his own body, even though the plaintiff had suffered no physical injuries. And again a State Court jury has awarded JEAN BERTHELOT $636,506.00 as damages as a result of the delay in the diagnosis of her breast cancer, because her doctor failed to order a mammogram, which was the standard of care.

GENERALIZED GRIEVANCE

The NCI argues that the loss of the right to a Spiral CT screening is a generalized grievance common to all members of the public and thus WILLIE NORMAN does not have

14. *Karp v. Cooley*, 493 F.2d 408, 420 (5th Cir. 1974).

15. *Lugenbuhl v. Dowling*, 701 So. 2d 447, 455-56 (La. 1997).

standing. However the loss of the right to Spiral CT screening is not a generalized grievance common to all members of the public. *See Henderson*[16] The right to Spiral CT screening is only common to the people who are at risk for lung cancer. The Supreme Court in *SCRAP*,[17] held that standing is not to be denied simply because many people suffer the same injury. To deny standing to people who are in fact injured, means that the most injurious and widespread Government actions could be questioned by no one. Just because 91 million other Americans are at risk for lung cancer and have lost the same right as WILLIE NORMAN, does not deny WILLIE NORMAN standing.

CAUSATION

The law mandated that both JEAN BERTHELOT's and WILLIE NORMAN's doctors order the cancer screening test for them, because that is what the standard of care is. The standard of care for ordering mammograms are the Federal and State mandated benefit laws, which mandate Medicare, Medicaid, insurance companies and HMOs to pay for mammography screening, most beginning at age 35. The standard of care for ordering Spiral CTs is the NCI's recommendation, because there are no laws mandating third party payors to pay for Spiral CTs, like there are for mammograms.

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16. *Henderson v. Stadler*, 287 F.3d 374, 380 (5th Cir. 2002).

17. *United States v. Students Challenging Regulatory Agency Procedures (SCRAP)*, 412 U.S. 669, 687, 37 L. Ed. 254, 93 S. Ct. 2405 (1973).

REDRESSABILITY

The moment the NCI recommends Spiral CT screening to detect lung cancer, it will immediately become the national and local standard of care for ordering Spiral CTs. Doctors will have a duty to order Spiral CTs for people at risk for lung cancer and third party payors will have a duty to pay for Spiral CTs.

The Louisiana Supreme Court recently in *Roberts*[18] reaffirmed the principle that where there is a uniform nationwide method for performing a particular medical procedure, an expert having knowledge of the method is qualified to testify and the testifying expert in this circumstance is not constrained by the need to have practiced in a similar community and locale and under similar circumstances.

In light of this jurisprudence, there obviously are nationwide medical standards. The NCI argues that its recommendations regarding cancer screening guidelines are not the nationwide medical standard of care. WILLIE NORMAN submits that the NCI's argument that its Spiral CT recommendations are not the standard of care is to ignore reality.

The web site Medscape Health, January, 16, 2002, reviewed for accuracy by physicians at Beth Israel Deaconess Medical Center (BIDMC), Harvard Medical School said: "Since it is still experimental, insurers won't pay for Spiral CTs. And the NCI says it should not be used to screen lung cancer yet."

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18. *Roberts v. Warren*, 791 So. 2d 1278, 1279 (La. 2001) (citing *Leyva v. Iberia Gen. Hosp.*, 643 So. 2d 1236 (La. 1974) (citing *Piazza v. Behrman Chiropractic Clinic, Inc.*, 601 So. 2d 1378 (La. 1992)).

On February 7, 1997, United States Senator Arlen Specter testified regarding the NCI's position on mammograms:

> We all know that if this test comes out and is accepted as not being indicated for women in their 40's, *the insurance companies won't pay for it and managed care won't pay for it* and then people won't have them available, I think this is an area which needs to be corrected.

Journal of the National Cancer Institute, Vol. 88, No. 2. January 17, 1996:

> New cancer screening guidelines from the U.S. Preventive Health Services Task Force — an independent panel convened by the U.S. Public Health Service — have drawn criticism from the American Cancer Society and the American College of Radiology. The Task force's 1989 guide to disease prevention is widely used: the 1995 guidelines update those published in 1989 *and are likely to be relied on for insurance reimbursement.*

New York Times, January 24, 1997:

> Right or wrong, health experts noted, it is a decision that cannot be ignored because it was rendered by a "consensus conference" of the National Institutes of Health, a sort of science court in which appointed experts act as jurors on difficult medical issues. Such conferences are a part of the national institutes consensus development programs and their decisions *are used by health insurance companies to set benefits and by doctors and medical associations to determine appropriate care.*

WILLIE NORMAN submits that the NCI is well aware that its guidelines are used by doctors, insurance companies, HMOs, Medicare and Medicaid as the standard of care for ordering and paying for medical tests and procedures, including mammograms and Spiral CTs.

ADMINISTRATIVE PROCEDURE ACT ("APA")

The APA waives sovereign immunity for suits seeking relief other than money damages from federal agencies or officials. 5 U.S.C. § 702. *See Transohio.*[19] Claims under the APA federal jurisdiction may be proper under the federal question statute 28 U.S.C. § 1331, the declaratory judgment statute, 28 U.S.C. §§ 2201-2202, or the mandamus statute, 28 U.S.C. § 1361.

EXHAUSTION REQUIREMENT

The Supreme Court in *Darby*[20] held Congress codified the exhaustion doctrine of actions brought under the APA in § 10(c). Where the APA applies, an appeal to "superior agency authority" is a prerequisite to judicial review *only* when expressly required by statute or when an agency rule requires appeal before review and the administrative action is made inoperative pending that review. Courts are not free to impose an exhaustion requirement as a rule of judicial administration where the agency action has already become "final" under § 10(c).

None of the Federal Statutes cited in NORMAN's complaint require an exhaustion of administrative remedies.

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19. *Transohio Savs. Bank v. Director, Office of Thrift Supervision*, 967 F.2d 598, 607 (D.C. Cir. 1992).

20. *Darby v. Cisneros*, 509 U.S. 137, 153, 113 S. Ct. 259, 2548, 125 L. Ed. 113 (1993).

The final agency action occurred on April 29, 1999 and again on September 23, 1999 when the NCI made the decision not to recommend Spiral CT screening, but to spend $200,000,000.00 DOLLARS conducting CLINICAL TRIALS to measure mortality benefits from detecting lung cancer early.

STANDARD OF REVIEW

Section 706(2)(A) of the APA requires a reviewing court to "hold unlawful and set aside agency action that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The Fifth Circuit in *Sid Peterson*,[21] held the court must determine if the Secretary has reasonably interpreted his own regulations.

The Secretary's interpretation should be affirmed unless, in light of the language and purpose of the regulation, it is unreasonable. "Courts should accept the agency's interpretation if it is reasonable in terms of the words of the regulations and the purposes of the statute, even though as an original matter, the court might have reached a different conclusion." *See Marcello.*[22]

The Supreme Court in *Motor Vehicle*[23] held an agency rule would be arbitrary and capricious if the agency has relied

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21. *Sid Peterson*, 274 F.3d at 308 (citing *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512, 129 L. Ed. 2d 405, 114 S. Ct. 2381 (1994); *Girling Health Care, Inc. v. Shalala*, 85 F.3d 211 (5th Cir. 1994)).

22. *Marcello v. Bowen*, 803 F.2d 851 (5th Cir. 1986).

23. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 77 L. Ed. 443, 458, 103 S. Ct. 2867 (1983) (citing *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947)).

on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that is counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise. The reviewing court should not attempt to make up for any deficiencies, or give a reasoned basis for the agency's action that the agency itself has not given.

The agency must examine the relevant data and articulate a satisfactory explanation for its action including a "rational connection between the facts found and the choices made." *See Burlington.*[24]

A rule may also be invalidated under the APA if an agency fails to explain the rule adequately. The agency's explanation must allow a reviewing court to understand what major issues of policy were discussed by the informal proceedings and why the agency reacted to them the way it did. *See Mt. Diablo.*[25]

WILLIE NORMAN submits that when the U.S. HOUSE COMMITTEE in "MISUSED SCIENCE," used the language: "cancer screening guidelines" and "Further, for example," the intent of the U.S. HOUSE COMMITTEE was for NCI to revise its reliance on CLINICAL TRIALS to determine cancer screening guidelines. Cancer screening guidelines apply not just to breast cancer, but include lung cancer as well.

The NCI argues that this Court does not have the power to stop them from flaunting the intent of the U.S. HOUSE COMMITTEE and the U.S. SENATE.

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24. *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962).

25. *Mt. Diablo*, 3 F.3d at 1234 (quoting *South Carolina ex rel. Tindal v. Block*, 717 F. 2d 874, 886 (4th Cir. 1983).

WILLIE NORMAN submits that this Court does have the power to compel the NCI to obey the order of the U.S. HOUSE COMMITTEE and the U.S. SENATE. WILLIE NORMAN submits that this is precisely the kind of agency action that is subject to review under the APA.

The U.S. HOUSE COMMITTEE in "MISUSED SCIENCE" told the NCI that it should change its policy of relying solely on CLINICAL TRIALS to determine cancer screening guidelines. The NCI after being told by the U.S. HOUSE COMMITTEE not to rely solely on CLINICAL TRIALS to determine screening guidelines in 1994, ignored the U.S. HOUSE COMMITTEE and relied on CLINICAL TRIALS in 1997, again not to recommend mammograms to women under 50 years of age.

In March 1997, the U.S. Senate voted 98-0 urging the NCI to "reinstate the pre-1993 mammography screening guidelines." U.S. Senator Arlen Specter called the NCI's mammography guidelines: "fraudulent." WILLIE NORMAN submits that these actions by the U.S. HOUSE COMMITTEE and the U.S. Senate are the intent of Congress that the NCI can not rely on CLINICAL TRIALS to measure mortality benefits to determine cancer screening guidelines and the NCI's continued reliance on CLINICAL TRIALS to measure mortality benefits from detecting lung cancer early is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. 5 U.S.C. § 706(2). *See Sid Peterson.*[26]

All the arguments the NCI uses against recommending Spiral CTs — false positives, false negatives, psychological consequences, radiation exposure, unnecessary biopsies and other invasive procedures are the same arguments the

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26. *Sid Peterson Memorial Hosp. v. Thompson*, 274 F.3d 301, 308 (5th Cir. 2001).

NCI used not to recommend mammograms to women under 50 years of age. Again the NCI has acknowledged a mortality benefit from mammography screening for breast cancer, after first denying there was a benefit.

Dr. Eschenbach, the Director of the NCI, in 2002, testified that from the patient's point of view, detecting cancer early adds to the quality of life of the patient, which is an extremely important contribution besides a mortality benefit. Dr. Eschenbach testified that detecting cancer earlier allows one to apply therapies that are going to be less mutilating and will have less impact on the patient's quality of life.

The NCI states that 50,000 people will participate, for the next 8 years, in its $200,000,000.00 DOLLAR CLINICAL TRIAL to measure mortality benefits from Spiral CT screening. Half of the people will receive an initial spiral CT and 2 subsequent yearly screens and half will have chest x-ray. The NCI will then wait and see who dies first, the people who had Spiral CT screening, or the people who had chest X -rays.

In "MISUSED SCIENCE" the U.S HOUSE COMMITTEE held that a CLINICAL TRIAL for mammograms would take 10 years and 1.5 million women to have statistical significance to measure mortality benefits. The U.S. HOUSE COMMITTEE also held that women are aware of mammography screening and it would be difficult to have a control group of 500,000 women who could not have mammograms.

WILLIE NORMAN argues in the light of the information and evidence the NCI has regarding the early detection of breast cancer including the mortality benefits and the enhancements to the quality of life from detecting breast cancer early, it is not ethical for the NCI to conduct a CLINICAL TRIAL with 25,000 people who will be screened for lung cancer and compare them to 25,000 people who do not get Spiral CT screening and then measure which group dies from lung cancer sooner.

Dr. Eschenbach, Director of the NCI, in 2002, testified that conducting a CLINICAL TRIAL for mammograms now, would not be a rational study. A CLINICAL TRIAL would be difficult to carry out under the NCI's current structure and it would be difficult to attract a sufficient number of women who would accept randomization by a flip of a coin. Dr. Eschenbach testified that he has serious concerns that a CLINICAL TRIAL for mammograms could be carried out in a reasonable period of time to be conclusive. WILLIE NORMAN submits that this same line of reasoning also applies to Spiral CTs.

NCI, Report of the Lung Cancer Progress Review Group, August 2001: "The target group for prevention and detection of smoking-related lung cancer in the United States is 91 million people (44 million former smokers and 47 million current smokers)."

NCI, Report of the Lung Cancer Progress Review Group, August 2001:

> Currently the vast majority of patients present with locally advanced or metastatic disease. Any significant change in the stage distribution at presentation has the possibility of making a profound impact on cancer death rates, given the prevalence of lung cancer. Unfortunately, this area of research has become *mired* in well-intentioned but ultimately counterproductive arguments about the merits of the necessity for randomized, controlled trials with overall mortality as the sole endpoint.

CONCLUSION

For the forgoing reasons WILLIE NORMAN submits that he does have standing to challenge the NCI's final decision not to recommend Spiral CT screening, but to spend the next 8 years and $200,000,000.00 DOLLARS measuring mortality benefits from detecting lung cancer early.

WILLIE NORMAN respectfully requests this Court to bring him and the other 91 million Americans, who are at risk for lung cancer, out of the **MIRE** and enter an injunction and order the NCI to recommend Spiral CT screening for him and all Americans who are at risk for lung cancer.

Respectfully submitted,

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APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT DATED AND FILED JANUARY 17, 2003

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 02-30590
Summary Calendar

WILLIE C. NORMAN,

Plaintiff-Appellant,

versus

UNITED STATES PUBLIC HEALTH SERVICE; TOMMY G. THOMPSON, SECRETARY, DEPARTMENT OF HEALTH & HUMAN SERVICES; DEPARTMENT OF HEALTH & HUMAN SERVICES; DAVID SATCHER, Assistant Secretary for Health and the director of the Office of Public Health and Science; OFFICE OF PUBLIC HEALTH AND SCIENCE; ANDREW VON ESCHENBACH, Director of the National Cancer Institute; NATIONAL CANCER INSTITUTE; RANDOLPH F. WYKOFF, Director of the Office of Disease Prevention and Health Promotion; OFFICE OF DISEASE PREVENTION AND HEALTH PROMOTION; UNITED STATES PREVENTIVE SERVICES TASK FORCE; JOHN M. EISENBERG, Director of the Agency for Healthcare Research and Quality; AGENCY FOR HEALTH CARE RESEARCH AND QUALITY,

Defendants-Appellees.

Appendix A

Appeal from the United States District Court
for the Eastern District of Louisiana
USDC No. 01-CV-3863-N

Before JONES, STEWART, and DENNIS, Circuit Judges.

PER CURIAM:*

Willie C. Norman appeals the district court's judgment dismissing his action for, among other things, lack of standing. Norman argues that he does have standing.

Norman, however, has failed to meet the three criteria needed for standing. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). Accordingly, we need not address any other ground for dismissal, and the judgment is AFFIRMED.

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* Pursuant to 5TH CIR. R. 47.5, the court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in 5TH CIR. R. 47.5.4.

APPENDIX B — ORDER AND REASONS OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF LOUISIANA DATED AND FILED APRIL 17, 2002

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

CIVIL ACTION

NO. 01-3863

SECTION "N"

WILLIE C. NORMAN

VERSUS

UNITED STATES PUBLIC HEALTH SERVICE, ET AL

ORDER AND REASONS

Before the Court is a Motion to Dismiss, or Alternatively, for Summary Judgment, filed by the defendants in this matter: United States Public Health Service, Tommy G. Thompson, United States Department of Health and Human Services, David Satcher, Office of Public Health and Science, Andrew Von Eschenbach, The National Cancer Institute ("NCI"), Randolph F. Wykoff, The Office of Disease Prevention and Health Promotion, The United States Preventive Services Task Force, John M. Eisenberg, and The Agency for Health Care Research and Quality (the "defendants"). For the reasons that follow, the motion is GRANTED.

Appendix B

I. *BACKGROUND*

Plaintiff, a smoker with no symptoms of lung cancer, brings this action (purportedly on behalf of all Americans at risk of lung cancer), seeking an order directing the defendants to recommend low-dose helical computed tomography ("Spiral CT") to detect lung cancer. Plaintiff alleges that, although he has been examined by doctors who know he is a smoker, no doctor has recommended that he receive Spiral CT.[1] He claims that this would not have happened if the defendants had recommended the test because such a recommendation would impose a duty on all physicians to recommend the test and a duty on Health Maintenance Organizations (HMO's) and Medicaid/Medicare to pay for it. Using this logic, plaintiff claims that the defendants owe him damages for depriving him of the right to determine what will be done to his body. He also seeks an order directing the defendants to recommend Spiral CT to detect lung cancer.

II. *LAW AND ANALYSIS*

Defendants move to dismiss plaintiff's claims pursuant to Rule 12(b)(1) and (b)(6) or, alternatively, Rule 56, on grounds (1) that plaintiff cannot satisfy the case or controversy requirement of Article III, and (2) that plaintiff cannot establish a cause of action against any of the defendants.

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1. Plaintiff does not allege that he asked his physicians for a Spiral CT screen. Nor does it appear that he has sued any of these physicians.

Appendix B

A. *Plaintiff Has Failed to Demonstrate a Case or Controversy.*

Defendants argue that plaintiff lacks standing to bring the instant action because he fails to meet the case or controversy requirement of Article III of the United States Constitution. The case or controversy requirement is the " 'irreducible constitutional minimum' of standing." *Bennett v. Spear*, 520 U.S. 154, 162 (1997). To satisfy it requires: "(1) that the plaintiff have suffered an 'injury in fact'—an invasion of a judicially cognizable interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) that there be a causal connection between the injury and the conduct complained of—the injury must be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court; and (3) that it be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Id.* at 167.

The party invoking federal jurisdiction—here, the plaintiff—"bears the burden of establishing these elements," and "each element must be supported in the same way as any other matter on which the plaintiff bears the burden of proof." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). Thus, to defeat summary judgment, "the plaintiff can no longer rest on . . . 'mere allegations,' but must 'set forth' by affidavit or other evidence 'specific facts,' . . . which for purposes of the summary judgment motion will be taken to be true." *Id.* Plaintiff has not met this burden.[2]

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2. The Complaint in this matter was verified by the plaintiff, and the Court has accepted as true each of the allegations therein.

First, plaintiff has failed to set forth any specific facts demonstrating a real, non-conjectural injury. For "a private individual to invoke the judicial power to determine the validity of executive or legislative action he must show that he has sustained or is immediately in danger of sustaining a direct injury as the result of that action." *Lujan*, 504 U.S. at 577. "[I]t is not sufficient that he has merely a general interest common to all members of the public."[3] *Id.* Here, plaintiff argues that his injury is that he, like all other Americans at

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3. The *Lujan* court explained the reasoning behind this rule:

> To permit Congress to convert the undifferentiated public interest in executive officers' compliance with the law into an 'individual right' vindicable in the courts is to permit Congress to transfer from the President to the courts the Chief Executive's most important constitutional duty, to 'take Care that the Laws be faithfully executed,' Art. II, § 3. It would enable the courts, with the permission of Congress, 'to assume a position of authority over the governmental acts of another and co-equal department,' . . . and to become 'virtually continuing monitors of the wisdom and soundness of Executive action.'. . . . We have always rejected that vision of our role. . . . [U]nder Article III, Congress established courts to adjudicate cases and controversies as to claims of infringement of individual rights whether by unlawful action of private persons or by the exertion of unauthorized administrative power. 'Individual rights,' within the meaning of this passage, do not mean public rights that have been legislatively pronounced to belong to each individual who forms part of the public.

Lujan, 504 U.S. at 577-78 (internal quotations and citations omitted).

risk for lung cancer, has lost the right to determine what will be done with his body as a result of the NCI's decision to further study Spiral CT rather than recommend it immediately, without further study, as a screen for all Americans at risk for lung cancer.[4] Thus, as a threshold matter, his claim of injury does not satisfy Article III standing requirements because it is held in common with the ninety-one million other Americans he claims are at risk for lung cancer. Moreover, plaintiff has presented no specific facts showing that he ever has asked anyone—physician or HMO—that he be given a Spiral CT screen. He simply alleges (1) that physicians who knew he was a smoker examined him without recommending a Spiral CT screen and (2) that his HMO will not pay for the test unless it is ordered by a covered physician. *See* Complaint at ¶¶ 29, 31, 32. Thus, he has failed to set forth specific facts showing that anyone, much less defendants, has denied him the right to self-determination. Nor has he shown any other non-conjectural injury.[5]

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4. The Court notes that *Lugenbuhl v. Dowling*, the case relied upon by plaintiff for the proposition that defendants have deprived him of self-determination, does not support the existence of a compensable interest under the circumstances alleged here. *See Lugenbuhl v. Dowling*, 701 So.2d 447, 455-56 (La. 1997) (holding that invasion of patient's right to privacy was compensable where surgeon disregarded that patient's consent to surgery was expressly conditioned on use of a specific procedure).

5. Plaintiff argues that he also has lost a part of his medical history—*i.e.*, the Spiral CT films that he would have had if defendants had recommend this test. This argument suffers from the same infirmities as the lost self-determination argument.

Second, even if plaintiff had set forth facts demonstrating a non-conjectural injury, which he has not, he nevertheless has failed to establish standing, for he has set forth no specific facts showing that this alleged injury was caused by the defendants and not "the independent action of some third party not before the court." *Bennett*, 520 U.S. at 167. He also has failed to show a likelihood that his alleged injury will be redressed by a favorable ruling. Plaintiff does not maintain that he personally was the object of any action by any of the defendants. Rather, he theorizes that his physicians surely would have prescribed Spiral CT screening, and his HMO surely would have paid for it, if the defendants had recommended that all persons at risk for lung cancer be so screened. Under these circumstances, it is "the burden of the plaintiff to adduce facts showing that [the choices of actors not before the Court] have been or will be made in such manner as to produce causation and permit redressability of injury." *Lujan*, 504 U.S. at 561. Plaintiff has failed to carry this burden. Accordingly, plaintiff also has failed to establish either the second or the third element of standing, and his claims must be dismissed.

Appendix B

B. *This Court Lacks Subject Matter Jurisdiction Over Plaintiff's Claim for Damages.*

Defendants argue that plaintiff's claim for damages would fail even if he had standing to bring it, for he has failed to exhaust his administrative remedies as required by the Federal Tort Claims Act ("FTCA"). The FTCA waives the government's sovereign immunity with respect to certain claims seeking damages for injuries caused by federal employees. However, the Court's subject matter jurisdiction over such a claim is "conditioned on compliance with 28 U.S.C. § 2675(a), which declares that 'an action shall not be instituted' unless the plaintiff has filed an administrative claim and either obtained a written denial or waited six months." *Price v. United States*, 69 F.3d 46, 54 (5th Cir. 1995) (quoting 28 U.S.C. § 2675(a)), *cert. denied*, 519 U.S. 927 (1996). "This requirement is jurisdictional, and may not be waived." *Id.* Plaintiff does not dispute that he has failed to satisfy the FTCA's jurisdictional requirement.[6] Accordingly, this Court has no jurisdiction over the claim for damages, and it must be dismissed.

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6. Instead, plaintiff responds to defendants' FTCA argument by urging the Court to certify a nation-wide class for purposes of injunctive relief only.

C. *Plaintiff's Remaining Claims Cannot Survive Summary Judgment.*[7]

Defendants argue that plaintiff cannot establish a cause of action against them under any of the statutes cited in the Complaint.[8] The Court agrees.

1. *Administrative Procedure Act*:

This Court had serious concerns as to whether it has jurisdiction over plaintiff's Administrative Procedure Act ("APA") claim. The APA authorizes review only of "final agency action." 5 U.S.C. § 704; *see also American Airlines*

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7. Because both plaintiff and defendants have submitted matters outside the pleadings, the Court will treat the Rule 12(b)(6) motion as one for summary judgment. *See* Fed. R. Civ. P. 12(b). "Summary judgment is proper 'if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.' " *Kee v. City of Rowlett, Texas*, 247 F.3d 206, 210 (5th Cir.), (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (quoting Fed. R. Civ. P. 56(c))), *cert. denied*, 122 S. Ct. 210 (2001). "A dispute over a material fact is genuine if the evidence is such that a jury reasonably could return a verdict for the nonmoving party." *Id.* (internal quotations omitted).

8. In addition to the FTCA and the statutes discussed below, plaintiff mentions in his complaint the Public Health Service Act and the Declaratory Judgment Act. However, as defendants point out, these statutes do not provide a cause of action to plaintiff, and plaintiff does not argue that they do.

Inc. v. Herman, 176 F.3d 283, 287 (1999).[9] To qualify as "final," the agency action in question "must mark the 'consummation' of the agency's decision making process[ ]—it must not be of a merely tentative or interlocutory nature." *Id.* (quoting *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (emphasis omitted)). Plaintiff does not complain of any agency action that satisfies this requirement. No agency has decided *not* to endorse use of Spiral CT as a screen for lung cancer. In fact, NCI just approved a $200 million eight-year trial to study whether screening with Spiral CT reduces mortality from lung cancer. *See* Defendant's Exh. B. It is this approval that plaintiff claims constitutes a final action reviewable by this Court under the APA. *See* Opp. Memo at p. 14 (Rec. Doc. 20). The Court disagrees that this decision to gather more facts is a final action reviewable by this Court. Indeed, one reason behind the finality requirement is "to let the agency develop the necessary factual background upon which decisions should be based." *United States Postal Serv. v. Notestin*, 857 F.2d 989, 993 (1988). Like *American Airlines*, this simply "is not a case in which 'no further administrative proceedings are contemplated.' " *American Airlines*, 176 F.3d at 292. Accordingly, the Court is without jurisdiction to review the decision under the APA.

Moreover, even if this Court did have jurisdiction to review the NCI's decision to conduct a study of the effects of using Spiral CT to screen for lung cancer, the plaintiff's APA claim would not survive summary judgment, for plaintiff has set forth no facts from which a fact-finder reasonably

9. Action that is merely "preliminary, procedural, or intermediate" is subject to review upon review of the final action. 5 U.S.C. § 704.

could conclude that the decision was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. *See* 5 U.S.C. § 706. Instead, the documents submitted that relate to Spiral CT screening for lung cancer[10] show careful assessment of the merits of further study through the use of careful procedures.

2. *Mandamus Act*:

Plaintiff concedes that mandamus is "an extraordinary remedy." Opp. Memo at p. 17 (quoting *Dunn-McCampbell Royalty Interest, Inc. v. National Park Service*, 112 F.3d 1283, 1288 (5th Cir. 1997)). It is "available only where government officials clearly have failed to perform nondiscretionary duties." *Dunn-McCampbell*, 112 F.3d at 1288. To obtain relief under the Mandamus Act, plaintiff "must demonstrate that a government officer owes [him] a legal duty that is a specific, ministerial act, devoid of the exercise of judgment or discretion." *Id.* "The legal duty must be set out in the Constitution or by statute, . . . and its performance must be positively commanded and so plainly prescribed as to be free from doubt." *Id.*

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10. In addition to submitting documents relating to Spiral CT screening for lung cancer, plaintiff has filed dozens of documents and other materials relating to the guidelines for using mammography as a screen for breast cancer. Counsel for plaintiff previously submitted these same materials to a different section of this Court in connection with a similar case filed against the defendants on behalf of a plaintiff diagnosed with breast cancer. *See Berthelot v. United States Preventative Services Task Force, et al*, No. 01-1854 (E.D. La. 2001) and No. 01-30920 (5th Cir. Feb. 4, 2002) (dismissing as frivolous plaintiff's appeal of Judge Barbier's dismissal of that action). This Court can find no relevance of these materials to the issues in the instant action.

Plaintiff maintains that NCI's decision to further study Spiral CT scans and its failure to recommend Spiral CT scanning of smokers absent such study constitute a breach of the defendants' ministerial duty to protect the public health and promote preventive health services. The Court disagrees. The performance of such duties entails enormous exercise of judgment. Indeed, they are the antithesis of ministerial. Accordingly, plaintiff's Mandamus Act claim must be dismissed.

D. *Injunctive Relief*:

Plaintiff seeks preliminary injunctive relief in the form of an Order compelling the NCI to recommend Spiral CT screening for plaintiff and for all American smokers and ex-smokers over age forty-five. To obtain a preliminary injunction, a party must show, *inter alia*, a substantial likelihood that he will prevail on the merits. *Walgreen Co. v. Hood*, 275 F.3d 475, 477 (5th Cir. 2001). For all the reasons discussed above, plaintiff has failed to demonstrate a likelihood of success on the merits under any theory.

III. *CONCLUSION*

Accordingly, for the foregoing reasons, **IT IS ORDERED** that the defendants' Motion to Dismiss, or Alternatively, for Summary Judgment is **GRANTED**.

New Orleans, Louisiana, this 17th day of April 2002.

s/ Kurt D. Engelhardt
KURT D. ENGELHARDT
UNITED STATES DISTRICT JUDGE